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Peter A. Clark,

Methotrexate and Tubal Pregnancies: Direct or Indirect Abortion?

by

Peter A. Clark, S.J., Ph.D.

The author is an Assistant Professor of Theology at St. Joseph's University, Philadelphia, where he teaches medical ethics. He is also the Bioethics Consultant for the Mercy-East Health System, also in Philadelphia.

A year and a half ago, a young couple in their mid-thirties came to me as a bioethicist, seeking advice concerning the morality of various fertilization procedures. Judy and Ray had been trying to conceive for three years with little success. After going through fertility testing it was determined that one of Judy's fallopian tubes was blocked and inoperable, but the other seemed functional. As a result, the fertility specialist prescribed clomid, which is a fertility medication. Ten months later Judy was pregnant. In the fourth week of her pregnancy it was determined that she had a tubal ectopic pregnancy. The embryo was implanted in her left fallopian tube and this presented a life-threatening situation due to the potential for hemorrhage. Her obstetrician presented her with the four current procedures for the management of tubal pregnancies. The first is expectant management, wherein the woman is closely monitored but there is no direct action. The reason for this is that statistics show that half of tubal pregnancies spontaneously resolve themselves.[1] The second, salpingectomy, involves a full or partial surgical procedure: wherein in the full procedure the entire fallopian tube containing the embryo is surgically removed, and the severed ends of the tube are brought together and sutured. The third, salpingostomy, involves making a linear incision, 2 cm in length or less, on the antimesenteric border immediately over the ectopic pregnancy. The embryo usually will extrude from the incision and can be carefully removed. Fourth, methotrexate treatment (MTX), the drug MTX, administered systemically or injected at the site, inhibits DNA synthesis so

that the otherwise normal implantation enzymatic activity ceases.[2] Judy's obstetrician recommended the non-surgical solution of MTX treatment, because it is the least medically invasive, the injection is given as an outpatient, and it eliminates the costs and the medical risks of hospitalization and surgery.[3] The question presented to me as a bioethicist was whether MTX treatment was morally justifiable by the Catholic Church?

Various factors have to be considered regarding this case. First, Judy is having numerous problems getting pregnant and after exploratory surgery it appears that her right fallopian tube is nonfunctioning. MTX treatment would preserve her functioning fallopian tube and allow for the possibility of future pregnancies. Second, Judy and Ray very much want to have children, but if they opt for full or partial salpingectomy, which the Church morally allows, they would never have their own biological children. Their chances for adoption are slim because of their financial status and their age. Third, prior to 1994, the *Ethical and Religious Directives for Catholic Health Care Facilities* were very specific about the procedures which were permitted in the management of a tubal pregnancy. Any procedure which removes the embryo from the ectopic site is prohibited. In the 1971 directives, specific procedures did not conform to the moral law.[4] In the revised 1994 edition nothing is stated about particular procedures which are licit. Directive 48 of the revised *Ethical and Religious Directives* states: "In case of extrauterine pregnancy, no intervention is morally licit which constitutes a direct abortion."[5] The Bishops no longer teach that specific procedures do not conform to the moral law. Instead, they emphasize the basic principle that any procedure, to be licit, must conform to the moral law regarding abortions.[6] There are a number of ethical questions surrounding this issue, but the focus is on the ethical ambiguity pertaining to whether MTX is a form of direct or indirect abortion.

The purpose of this article is threefold: first, to examine the medical reality of a tubal pregnancy and the function of MTX as a viable medical treatment; second, to examine the ethical arguments for and against the use of MTX as a viable option in the case of a tubal pregnancy; third, to give an ethical analysis of these arguments to determine if MTX is morally justifiable in the case of a tubal pregnancy.

Tubal Pregnancy and Methotrexate

An ectopic pregnancy is one in which implantation occurs outside the endometrium and the endometrial cavity, such as in the cervix, uterine tube, ovary, or the abdominal or pelvic cavity. It continues to be the leading

cause of maternal morbidity and a major reason for reduced child-bearing potential among women of reproductive age. It is also the leading cause of pregnancy-related deaths during the first trimester of pregnancy. Approximately 95% of ectopic pregnancies occur in the fallopian tube. The rate of occurrence of ectopic pregnancy increased from 4.5 to 16.8 per 1,000 pregnancies between 1970 and 1987.[7] In 1995, the Centers for Disease Control and Prevention (CDC) estimated a rate of 19.7 ectopic pregnancies per 1,000 reported pregnancies. The CDC also reported that ectopic pregnancy-related deaths made up 9% of all maternal deaths and most of these deaths were due to tubal rupture.[8] The destruction of the normal tubal anatomy remains the major cause of ectopic pregnancy and is the explanation in about 50% of the cases. The histologic changes associated with pelvic inflammatory disease (PID) are found in about half of the tubes removed for an ectopic pregnancy. Other important risk factors include a previous operation for an ectopic pregnancy, previous tubal ligation, and conservative tubal procedures for the treatment of infertility. Related to PID are other risks such as age and ethnicity.[9] Although the use of oral contraceptives reduces the risk of ectopic pregnancy by about 90%, the use of an intrauterine device may increase the risk, in that when pregnancy does occur, (<2%), about 4% to 17% will be an ectopic. The other occurrences of an ectopic pregnancy are probably a result of hormonal imbalance, aberrations in tubal mortality, and abnormalities in the embryo, including transmigration to the opposite tube and genetic abnormalities.[10]

Diagnosis of an ectopic pregnancy is as unpredictable as the ectopic pregnancy itself. Many times the patient may not become symptomatic until rupture occurs. Approximately 70% of those patients not diagnosed early present with the classic triad of symptoms, consisting of amenorrhea, abdominal pain and abdominal vaginal bleeding. Initial signs of an ectopic pregnancy are cramping pain and spotting shortly after the first missed menstrual period. Gradual hemorrhage from the fallopian tube causes pain and pressure, but rapid hemorrhage results in hypotension and shock. Usually, uterine bleeding precedes these events as human chorionic gonadotropin (hCG) levels decrease.[11] Physical examination shows signs of hemorrhage, shock, and lower abdominal peritoneal irritation that may be lateralized. Pelvic examination will show the uterus to be enlarged, the cervix to be tender to motion, and a tender mass may be palpated in one adnexum. The cul-de-sac may bulge. Pain is often experienced in the pelvis or abdomen, and usually occurs approximately in the fourth to sixth week of gestation. Rupture and intraperitoneal bleeding occurs at six to ten weeks. Abdominal and pelvic tenderness is the most consistent sign.[12] Either transcervical or abdominal ultrasonography can assist in diagnosis,

and a laparoscopy can also be helpful. Advancements in medical technology and diagnostic techniques have allowed the discovery of an ectopic pregnancy before rupture to have risen from one in every 136 deliveries to one in every 79 in the last ten years.[13]

The prognosis for an ectopic pregnancy has been guarded. Approximately one-third of the patients became infertile, one-third had subsequent pregnancy loss (miscarriage or repeat ectopic), and one-third had a full-term intrauterine pregnancy. However, with conservative surgical treatment and nonsurgical treatments, viable pregnancy rates of 50% to 85% have been reported. Results are better if the oviduct has not ruptured, emphasizing the importance of early diagnosis. This early diagnosis is made possible by the use of vaginal ultrasound and serum quantitative beta-hCG (human chorionic gonadotropin) determinations.[14]

Biologically, in a normal uterine implantation, by the fifth day after fertilization, the conceptus enters the blastocyst stage (preimplantation embryo) of development. The blastocyst has arrived in the uterus and implantation usually occurs in the front or back wall of the endometrial cavity near the fundus. At the blastocyst stage the embryo has divided into two major portions, the inner cell mass called the cytoblast, which will develop into the fetus, and the outer cell mass called the trophoblast (temporary structure), which gives rise to the placenta that attaches the conceptus to the uterine wall and nourishes the embryo. In a tubal implantation, the trophoblast attaches itself to the wall of the fallopian tube. The trophoblast cells secrete protein-digesting enzymes which enable the blastocyst to secure itself to the mucosal layer of the fallopian tube. It is the trophoblast, not the cytoblast, that causes the life-threatening pathology. Due to the small size of the fallopian tube, the embryo will be unable to develop and the mother's life will be threatened because of the inevitable rupture and hemorrhaging of the tube.[15]

As stated earlier, the four current procedures to treat a tubal pregnancy are expectant management, salpingectomy (full or partial), salpingostomy, and MTX treatment. The Catholic Church allows for expectant management and a full or partial salpingectomy because neither would constitute a direct abortion. The salpingectomy would be an indirect abortion by the principle of double effect. The direct intention in a salpingectomy is to remove a pathological organ and a foreseen but unintended consequence is that the nonviable embryo is terminated. A salpingostomy is morally prohibited because it is a direct abortion. The direct intention of the physician is to terminate the embryo. MTX treatment is morally ambiguous because it is the trophoblast that is directly affected, not the cytoblast. The direct cause of the pathology – the trophoblast – is destroyed, and indirectly the cytoblast is separated from

the wall of the fallopian tubes and dies. To understand this direct/indirect distinction it is important to first understand how MTX functions.

MTX is a highly toxic folic acid analog which inhibits dehydrofolate reductase and halts the synthesis of deoxyribonucleic acid (DNA) and cell multiplication in the trophoblastic tissue. Studies have shown that trophoblastic cells are very sensitive to MTX. This toxic drug makes the trophoblast unable to produce the protein-digesting enzymes necessary for its penetration into the tissue of the fallopian tube.[16] Prior to giving the injection of MTX, all patients should have a normal platelet and white blood cell count, normal liver enzymes, and renal function. After this has been determined, patients with subnormally rising hCG titers <2000mIU/ml are given a dose of MTX (50mg/m^2) as an intramuscular injection. Following initial treatment, a hCG titer is obtained on day four and day seven. The hCG titer in day four will generally be higher than the hCG titer in day one. If the hCG titer on day seven is less than the hCG titer on day four the hCG titer is followed weekly until negative. If this is not the case and the hCG is not declining, a second dose of MTX is given (50 mg/m^2), and the hCG titers are repeated on days four and seven as with the first course of treatment. Patients should be informed that the failure rate for those with an unruptured ectopic pregnancy <3.5 cm in greatest dimension is 5%. Also, the majority of patients will have an increase in abdominal-pelvic pain during treatment.[17]

The major function of the MTX treatment is that it interferes with DNA synthesis and cell multiplication. Since the trophoblastic tissue is actively proliferating it is very sensitive to the effect of MTX. Ethicist Albert Moraczewski explains it this way: "Because the trophoblastic cells are rapidly dividing they are affected more quickly and fully than cells of the embryo proper. These are relatively quiescent until an adequate supply of nourishment is available to them. Once the synthesis of proteolytic enzymes stops (as a result of MTX), the trophoblastic activity ceases and further damage is prevented."[18] After the trophoblast ceases growth, the embryo will die and the dead tissue is absorbed into the fallopian tube as part of the natural healing process. Dr. Eikicki Kojima, of the Tokyo School of Medicine, explains that, "the process of this therapy (intratubal MTX) is similar to the natural healing process of ectopic pregnancy (such as would occur in expectant management) because the MTX selectively suppresses the growth of the trophoblast and induces necrosis; the necrotic tissue is absorbed in the fallopian tube."[19] Medically, according to a study done by Dr. Thomas Stovall, of the Bowman School of Medicine at Wake Forest University, "methotrexate management of the unruptured ectopic pregnancy <3.5 cm in greatest dimension offers clinical efficiency, minimal side-effects, minimal lost work time, 95% success rates, reproductive

outcomes similar to those obtained with surgery, and a cost profile which results in considerable savings when compared with surgical management."[20] However, ethically, the question which still remains is whether or not this is a direct or an indirect abortion? If the effects of MTX on the trophoblast cannot be viewed as a separate effect from that which is caused to the cytoblast, it is a direct abortion and morally unjustifiable. If the effects of MTX on the trophoblast can be separated from the effects on the cytoblast, it is an indirect abortion and does not appear to violate the *Ethical and Religious Directives for Catholic Health Care*. To determine which is true, an ethical analysis of arguments for and against the use of MTX treatment needs to be examined.

Arguments For and Against Methotrexate

The ethical argument for the use of MTX is directly tied to the 1994 revision of the *Ethical and Religious Directives for Catholic Health Care Services*, which no longer teach that certain procedures do not conform to the moral law. What the directives state is that one can never allow for a procedure which directly intends the destruction of a viable fetus.

In the case of a tubal pregnancy three medical factors are paramount. First, the implantation is in an abnormal site, as a result, this is a life-threatening situation for both the mother and the embryo. Second, this is a nonviable embryo, because the embryo will never be able to develop and come to term in its present location. Third, the trophoblast is directly injuring the tissue of the mother's fallopian tube and the result, if not treated, is threatening to the mother's life. The ethical argument for the use of MTX focuses on whether one can differentiate between the embryo and the placenta, or the cytoblast and the trophoblast.

Proponents for the use of MTX in tubal pregnancies argue that it is ethically justifiable because the direct intention is to inhibit the synthesis of DNA which will stop the destructive action of the trophoblastic cells. Arguments in favor of the use of MTX will focus on two main moral principles: the three-font principle and the principle of double effect.

In the Catholic moral tradition, the three-font principle has been used to determine the morality of a human action. One must consider three distinct elements: the intention (the reason the person is performing the action), the moral object (the precise good freely willed in this act) and the circumstances (person, place, time, conditions of persons involved, etc.). For a human action to be morally justified all three elements need to be morally good. The intention of the physician in his or her use of MTX is to preserve the health and life of the mother and to protect her fallopian tube for future reproductive activity, not the direct termination of the embryo.

The termination of the nonviable embryo is a foreseen but unintended consequence. The moral object is to stop the destructive nature of the trophoblast by stopping future protein synthesis. The immediate goal is not to attack the life of the embryo. Rather, MTX stops the pathological trophoblastic implanting process that is threatening the mother's life. As a result, the trophoblast dies, the cytoblast's death follows subsequently, and the mother's life is no longer directly threatened.[21] The circumstances are unlimited in number: the woman's age, health, etc. The most relevant circumstance is that the pregnancy is ectopic, that is, it is in the fallopian tube which cannot sustain the pregnancy and as a result, the mother's health and life are directly threatened and the embryo is nonviable.[22] All three elements of the action appear to be good. The intention is good, that is to preserve the health and life of the mother. The moral object is good, that is, MTX will stop the destructive action of the cells in the trophoblast, which is causing the life-threatening condition to the mother. The moral object is not a direct attack on the life of the embryo, even though the foreseen but unintended consequence of the action will be the death of the nonviable embryo. The circumstances are good, because unless something is done both the mother and the embryo will die.

Proponents of MTX also argue that it is morally justified by the principle of double effect. The principle of double effect is a fundamental principle in Roman Catholic moral theology. As the name implies it refers to one action with two effects. One effect is intended and morally good; the other is unintended and morally evil. It is not an inflexible rule or mathematical formula, but rather an efficient guide to prudent moral judgment in solving difficult moral dilemmas.[23] Historically, many ethicists believe the premises for the principle can be found in the writings of Thomas Aquinas in his famous explanation of lawful killing of another in self-defense in the *Summa Theologicae II*, q.64,a.7c. However, other ethicists argue that the four conditions of the principle were not finally formulated until the mid-nineteenth century by Jean Pierre Gury.[24] The principle of double effect specifies four conditions that must be fulfilled for an action with both a good and a bad effect to be morally justified.

> 1) The action, considered by itself and independently of its effects, must not be morally evil. The object of the action must be good or indifferent.
> 2) The evil effect must not be the means of producing the good effect.
> 3) The evil effect is sincerely not intended, but merely tolerated.
> 4) There must be a proportionate reason for performing the action, in spite of the evil consequence.[25]

The principle of double effect is applicable to the use of MTX for a tubal pregnancy because it has two effects, one good and the other evil. The good effect is that the mother's health is preserved and the evil effect is that the embryo dies. Proponents argue that MTX is morally justified because it meets the four conditions of the principle of double effect. The first condition allows for the injection of MTX because the action in and of itself is good, in that in stopping the action of the destructive trophoblast the mother's health and life are preserved. The action does not directly kill the human embryo. The second condition allows for the injection of MTX because the good effect is not caused by means of the evil effect. MTX is an anti-trophoblastic agent, which directly stops further protein synthesis. MTX achieves its effect by directly impacting on the trophoblast, not the cytoblast. Therefore, the growth of the trophoblast is stopped without causing the death of the human embryo. The third condition is met because the direct intention of the MTX injection is not to kill the embryo, whose life is as sacred as that of its mother, but to stop the destructive action of the trophoblast. Finally, there is a proportionate reason for allowing for MTX because the trophoblast is causing a serious pathological condition, which is life-threatening to the mother and there is no way to save the life of the embryo. The foreseen but unintended side effect of the MTX treatment is the termination of the nonviable cytoblast, which is eventually absorbed by the mother's body. The proportionately grave reason that allows for the use of MTX is the real and imminent threat of death to the mother. Moraczewski argues that, "according to available evidence, the eventual death of the trophoblast is not the means by which further growth and proteolytic activity is stopped. Rather, the death of the trophoblast follows eventually from the cessation of cell division."[26] Therefore, since the use of MTX meets all four conditions of the principle of double effect, one would be morally justified in using MTX in the case of a tubal pregnancy.

Opponents to the use of MTX for tubal pregnancies argue that MTX is a form of direct abortion. Their argumentation is twofold: first, one cannot separate the trophoblast from the cytoblast. They are two composite parts of the human embryo and both are vital to the good of the unborn child. Ethicist William E. May of the John Paul II Institute for Studies on Marriage and Family argues that the trophoblast "is a *vital organ* of the unborn baby during gestation. Although it is discarded later on, it must be regarded as an integral part of the body of the unborn child."[27] The human embryo is an innocent person and MTX causes the direct termination of the unborn child. May states, "One chooses to use MTX precisely because one knows that it will destroy the trophoblast, i.e., a vital organ of the unborn child. Its 'therapeutic' effect is achieved only by means of its lethal effect

on the unborn child. Moreover, the 'therapeutic effect' does *not* benefit the unborn child but the mother, and does so only because its nontherapeutic effect destroys the trophoblast of the unborn child, thus causing its death."[28] When one attacks the trophoblast one is directly attacking the unborn child.

Second, MTX is not morally justified by the principle of double effect. First, the action of administering MTX, considered in and of itself, is morally evil. MTX directly kills the unborn child. Second, the evil effect – the death of the unborn child – causes the good effect, the preservation of the mother's life. MTX directly impacts on the unborn child. As a result, the effects of MTX do not benefit the unborn child, who is killed as a result of its use; instead, it benefits the mother. Third, the evil effect is directly intended. MTX does not remove damaged tubal tissue as Moraczewski argues; instead, opponents believe that the direct intention of using MTX is to remove the unborn child from the fallopian tube. MTX directly attacks the unborn child for the benefit of the mother.[29] Finally, there is not a proportionate reason for allowing for MTX because there is a viable option – a full or partial salpingectomy. The only reason that MTX is used and justified is because it preserves the fertility of the affected fallopian tube.[30] The preservation of a woman's fertility cannot be justified by the direct death of an unborn child.

May argues that if MTX is morally justified for tubal pregnancies, others may view this as a legitimate way to perform direct abortions. It will open the door to the "slippery slope."[31] His claim is supported by Dr. Bernard Nathanson. In an address Nathanson gave at the National Law Center of Virginia on January 19, 1998, he stressed that "in coming years the drive to use chemical means, predominately methotrexate, to perform abortions will become intense because this will enable 'respectable' doctors to offer the 'service' of abortion in their private offices. The use of MTX to manage tubal pregnancies can only be regarded as a direct abortion and an attack on the life of the unborn."[32] MTX treatment sets a dangerous precedent and the logical consequences that may follow seem inevitable. Opponents believe that their arguments against the use of MTX for tubal pregnancies are firmly grounded in the Catholic moral tradition. MTX directly terminates the life of the unborn child for the benefit of the mother. "Even if its death is not precisely the means chosen, one cannot exclude from the means chosen the intentional violation of the bodily integrity of the unborn child and the causing of its death, and doing so, not for its benefit, but for the benefit of another."[33] Therefore, the only morally justifiable procedure that can be used with a tubal pregnancy is a partial or full salpingectomy, because the procedure is performed on the mother, and

the death of the unborn child is not part of the procedure but a side effect that one does not directly intend.

Ethical Analysis

I believe that the use of MTX for tubal pregnancies is morally justified both by the three-font principle and the principle of double effect. The intention of the physician is to preserve the health and life of the mother, the object of the action is to stop the destructive enzymatic activity of the trophoblast, and the circumstances of a tubal pregnancy warrant such an action. The result is that the mother's life is preserved. A foreseen consequence of this action is the death of the embryo but this is not intended as a means or an end. What is directly intended is to stop the DNA synthesis so that the life-threatening condition to the mother is avoided.

I also agree with Moraczewski that the use of MTX is morally justified by the principle of double effect. The intention of using MTX is not the direct killing of the embryo but the preservation of the mother's health and life. The embryo's death is unintended. The death of the embryo is not what preserves the health and life of the mother; it is causally connected with the life-saving action. The evil effect of killing the embryo is not part of what the physician intends to do when using MTX, but is brought about in doing what one does.[34] Tuohey argues that, "It is true that in moving from the ectopic site to the trophoblast as the object of the procedure one is moving materially closer to the removal of the embryo itself as the means to the end of saving the woman's health and well-being. However, it is not correct to say that one is moving closer to the embryo. The conditions of the principle of double effect are not violated. As long as it is the trophoblast which causes the life-threatening hemorrhage, the procedure materially touches the trophoblast as its object, and neither the second nor third conditions are violated."[35] This leads to the fourth condition: is there a proportionate reason for permitting the use of MTX? I would argue that the justification of MTX by the principle of double effect rests on whether there is a proportionately grave reason for causing the unintended death of the embryo.

Proportionate reason refers to both a specific value and its relation to all the elements (including premoral evils) in the action.[36] The specific value in using MTX is to preserve the health and life of the mother. The premoral evil, which will inevitably come about by trying to achieve this value, is the foreseen but unintended death of the human embryo. The moral question is whether the value of preserving the health and life of the mother outweighs the premoral evil of the foreseen but unintended death of the nonviable human embryo. To determine if a proper relation exists

between the specific value and the other elements of the act, ethicist Richard McCormick, S.J., proposes three criteria for the establishment of proportionate reason:

> 1) The means used will not cause more harm than necessary to achieve the value.
> 2) No less harmful way exists to protect the value.
> 3) The means used to achieve the value will not undermine it.[37]

The application of McCormick's criteria to the use of MTX for a tubal pregnancy supports the argument that there is a proportionate reason for allowing this procedure. First, the use of MTX will cause the least amount of harm to achieve the value of preserving the mother's health and life. The value of the mother's life and the life of the embryo are equal; however, there is no chance that the embryo will survive under any circumstances. MTX will not only save the mother's life but also will preserve the fertility of her fallopian tube for possible future pregnancies. Second, there is no less harmful procedure available to protect the value of the mother's health and life. It is true that a salpingectomy will save the mother's life but it will not preserve the fertility of her fallopian tube. MTX treatment is less invasive and less costly and it is the least harmful procedure for the mother; therefore, it seems to be the best means available at the present moment. Third, the use of MTX does not undermine the value of human life. One can argue convincingly that MTX affects the destructive action of the trophoblastic cells directly, and as a result the trophoblast and the cytoblast die. In the process, it preserves the value of human life, because the mother's life is preserved and the death of the nonviable embryo is a foreseen but unintended consequence. May's argument that MTX directly attacks the unborn child because the trophoblast is a vital organ of the unborn child during gestation is incorrect. The direct attack is on the trophoblastic cells not the unborn child.

A basic rule of Christian ethics based in love is that when confronted with several possibilities, one ought to do that which will contribute the most to the well-being and development of persons and their social relations and to avoid as much as possible those elements that would harm or hinder this well-being.[38] MTX will certainly contribute to the well-being and development of affected mothers because this procedure will preserve the fertility of their fallopian tube and therefore allow for the possibility of future pregnancies and the gift of life. It seems clear that there is a proportionate reason for allowing MTX treatments for tubal pregnancies, therefore, it is morally justified under the principle of double effect.

The ethical dilemma remaining is that the proponents and opponents of MTX base their moral arguments on specific interpretations of the principle of double effect. Both sides contend that they have a solid moral argument for their respective positions. The result is a lack of moral certitude regarding the legitimacy of MTX treatment according to the 1994 revision of the *Ethical and Religious Directives for Catholic Health Care Services*. In moral terms, there is a legitimate doubt of law. The Catholic moral tradition has always made provisions for situations where there are legitimate doubts of fact about the existence, content or application of a particular moral obligation or a doubt of law. When there are serious doubts of fact or law one may employ the principle of probabilism. Probabilism states that "if the lawlessness of an action is doubtful one may follow a solidly probable opinion which favors liberty of action, even if the opposite is more probable."[39] A solidly probable opinion can be determined both intrinsically and extrinsically. "Probability is said to be intrinsic when the reasons for an opinion are cogent but not conclusive; it is called extrinsic when the authority, learning, prudence, of other people are taken as proof that the opinion in question is a probably true opinion."[40] A doubt of law pertaining to MTX treatments is quite evident. Tuohey argues "now that the Bishops no longer explicitly state that the law applies to procedures which are a 'separation of the embryo or fetus from its site within the part,' one may form the probable opinion that some procedures which do just that are nevertheless licit when the procedure may be characterized in such a way as to specify the object as not being the removal of an embryo, but the detaching of the trophoblast."[41]

I believe the principle of probabilism is applicable in this situation and further confirms the moral justification for the use of MTX to treat a tubal pregnancy. An intrinsic solidly probable opinion exists for the use of MTX because a direct abortion applies to the direct removal and killing of the unborn child. Since MTX directly affects the trophoblast and not the cytoblast, it is doubtful that the law regarding direct abortions pertains to protection of the trophoblastic matter. Furthermore, an extrinsic solidly probable opinion exists because a number of eminent moral theologians, such as Morczewski and Tuohey, have argued convincingly for the moral justification of MTX. I believe others, such as Germain Grisez, Joseph Boyle and Patrick Lee, from their respective writings, would also agree to the use of MTX, because the death of the human embryo is a foreseen but unintended result of the MTX treatment.[42] These moral theologians are eminent authorities in this field; therefore, their opinions regarding MTX as morally justified serve as a solidly-extrinsic probable opinion, notwithstanding the views of William E. May, Kevin Flannery, S.J., etc.,

who argue that they have also presented solidly probable opinions for their positions. [43]

Conclusion

This paper has presented a solidly probable argument for the use of MTX treatment in the case of a tubal pregnancy. This argument is based on the fact that MTX attacks the destructive activity of the trophoblastic cells directly, and a foreseen but unintended side effect is that the trophoblast and the embryo will die as a result of this treatment. Since the revised 1994 *Ethical and Religious Directives for Catholic Health Services* are ambiguous on whether they would allow for this medical procedure, and since a solidly probable argument, supported both by intrinsic and extrinsic opinions, upholds this procedure as morally licit, I believe it would be morally justifiable to advise Judy to use MTX as a licit procedure for the management of her tubal pregnancy. Her use of MTX is grounded in the Catholic moral tradition and is supported not only by the three-font principle and the principle of double effect, but also by the principle of probabilism. However, due to the moral ambiguity surrounding this medical treatment, dialogue and debate should continue among medical and ethical professionals until the Holy See makes a judgment on this specific medical procedure. We cannot stand idly by and in effect deny our fellow Christians an acceptable medical procedure that has a solid moral basis because we fear it might be abused in the future. Failure to act due to fear of possible abuse would be far more detrimental, because it would undermine the very foundation upon which Catholic moral theology is based.

References

1. For a more detailed analysis of expectant management, see A.J. Garcia, J.M. Aubert,et al, "Expectant Management of Presumed Ectopic Pregnancies," *Fertility & Sterility*, 48 (1987):395.

2. Albert S. Moraczewski, O.P., "Ectopic Pregnancy Revisited," *Ethics & Medics* 23 (March 1998): 3. See also, F. Gary Cunningham, M.D., et al, *Williams Obstetrics*, 19th edition (Norwalk, CT: Appleton & Lange, 1993), 705-709.

3. In 1991, a retrospective review of all patients treated for an ectopic pregnancy was done at San Francisco General Hospital. The purpose was to estimate the potential annual cost savings of MTX therapy for ectopic pregnancy. Direct costs were based on review of the hospital's billing statements, whereas indirect costs

were based on literature estimations. Of the 50 ectopic pregnancies treated, it was estimated the 15 (30%) were MTX eligible. The average total direct cost of the surgical cases was $10,509 compared with $1,495 for MTX treatment. It was calculated that the potential annual national cost savings would be in excess of $280 million. For a more detailed analysis, see M.D. Creinin and A.E. Washington, "Cost of Ectopic Management: Surgery Versus Methotrexate," *Fertility & Sterility* 60 (1993): 963-969. See also, A.E. Washington and P. Katz, "Ectopic Pregnancy in the United States: Economic Consequences and Payment Source Trends," *Obstetrics and Gynecology* 81 (1993): 287-292; and John F. Tuohey, "The Implications of the *Ethical and Religious Directives for Catholic Health Care Services* on the Clinical Practice of Resolving Ectopic Pregnancies," *Louvain Studies* 20 (1995): 43. In 1998 the average cost for a 200 milligram 10 ml vile of methotrexate was $95.00.

4. Directive 16 states: "In extrauterine pregnancy the affected part of the mother (e.g., cervix, ovary, or fallopian tube) may be removed, even though fetal death is foreseen, provided that: (a) the affected part is presumed already to be so damaged and dangerously affected as to warrant its removal, and that (b) the operation is not just a separation of the embryo or fetus from its site within the part (which would be a direct abortion from a uterine appendage) and that c) the operation cannot be postponed without notably increasing the danger to the mother." See *Ethical and Religious Directives for Catholic Health Care Facilities*, no. 16 (Washington D.C.: United States Catholic Conference, 1971).

5. National Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, no. 48 (Washington, D.C.: United States Catholic Conference, 1995): 20. It should be noted that there is a footnote to directive 48, concerning the meaning of direct abortion, referring back to directive 45, "Abortion (that is, the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus) is never permitted." Ibid., 19.

6. Tuohey, 42.

7. Michel E. Rivlin, M.D., "Ectopic Pregnancy," in *Manual of Clinical Problems in Obstetrics and Gynecology*, 4th edition, eds. Michel E. Rivlin, M.D. & Rick W. Martin, M.D. (Boston, MA: Little, Brown and Company, 1994), 10.

8. See Danny Saxon, M.D., et al, "A Study of Ruptured Tubal Ectopic Pregnancy," *Obstetrics & Gynecology* 90 (July, 1997): 46. See also Centers for Disease Control and Prevention, "Ectopic Pregnancy - United States, 1990-1992," *Morbidity and Mortality Weekly Report (MMWR)* 44 (1995): 46-48.

9. Rivlin, 10. Rivlin goes on to explain that there is a threefold increased incidence in women older than 35 years of age versus those younger than 35 and a 60% higher risk in black or Hispanic women than in white women. Ibid. There is also a geographical effect in the distribution of ectopic gestation: in the West Indies one

pregnancy in 28 is ectopic; abdominal pregnancy is much commoner in African countries than in the Western world and cervical pregnancy is more common in Japan See Betty Sweet, R.N., *Mayes' Midwifery: A Textbook for Midwives*, 12th ed. (London: Baillière Tindall, 1997), 520.

10. Rivlin, 10. Hormonal factors that have been implicated with an increased incidence of ectopic pregnancy include the use of the progesterone mini-pill, postcoital estrogens, and the progesterone-containing intrauterine device. Ibid.

11. HCG stimulates the corpus luteum in the ovary to continue secreting high levels of estrogen and progesterone in order to maintain the integrity of the pregnancy. For a more detailed analysis, see Robert Berkow, M.D., *The Merck Manual of Diagnosis and Therapy*, 16th ed. (Rahway, NJ: Merck Research Laboratories, 1992), 1850.

12. Rivlin, 10-11; see also Berkow, 1868; and Cunningham, et al, 698-705.

13. S.J. Orsy, "New Options for Diagnosis and Treatment of Ectopic Pregnancy," *Journal of the American Medical Association* 267 (1992): 534-537.

14. Rivlin, 12.

15. Albert Moraczewski, "Managing Tubal Pregnancies:Part II," *Ethics & Medics* 21 (August 1996): 3.

16. Ibid. Moraczewski states that, "MTX is most effective against rapidly dividing cells as cancer cells, hair follicles, and fetal cells (especially trophoblastic cells). One study found that rapidly dividing cells such as cancer cells were at least one thousand times more sensitive to MTX than normal cells." Ibid. It should be noted that MTX treatment applications in obstetrics and gynecology dates back to 1956 when Li, et al, first reported its use on the treatment of gestational trophoblastic disease. For a more detailed account, see M.C. Li, R. Hertz, and D.B. Spencer, "Effect of Methotrexate Therapy Upon Choriocarcinoma and Chorioadenoma," *Procedures in Social Experimental Biological Medicine* 93 (1956): 361.

17. Thomas G. Stovall, "Medical Management of Ectopic Pregnancy," *Current Opinion in Obstetrics & Gynecology* 6 (1994): 513. Stovall explains that as a result of increased abdominal-pelvic pain, "it is often difficult to distinguish this normal increase in pain from pain that is associated with ectopic pregnancy rupture...The cause of this pain is unclear. Methotrexate is known to induce abdominal pain and it is also possible that the patient may have some bleeding from the end of the tube which causes peritonitis." Ibid.

18. Moraczewski, "Ectopic Pregnancy Revisited," 4. See also Lisa Cannon and Hanna Jesionowska, M.D., "Methotrexate Treatment of Tubal Pregnancy," *Fertility & Sterility* 55 (June 1991): 1033-1037.

19. Eikichi Kojima, et al, "Treatment of Unruptured Tubal Pregnancy with Intratubal MTX Injection under Laparoscopic Control," *Obstetrics and Gynecology* 75 (April 1990): 725.

20. Stovall, 514.

21. Moraczewski argues that "the critical point in this analysis is the moral object. To remove any ambiguity here, the term *moral object* means: 'the proximate end of a deliberate decision which determines the act of willing on the part of the acting person' (John Paul II, *Veritatis Splendor*, 78). The moral object is the precise, proximate objective, seen as a good (real or apparent), which is *freely chosen in this particular act by the person.* It must be carefully distinguished from the intention (with which it is often confused). The intention is *the reason* why the person wants to intervene with MTX: the moral object is *the immediate goal* to be achieved by the use of MTX and chosen by the person as contained in the intention." Moraczewski, "Managing Tubal Pregnancies: Part II," 4. Emphasis in the original.

22. Ibid., 3-4.

23. Joseph Mangan, S.J., "An Historical Analysis of the Principle of Double Effect," *Theological Studies* 10 (March 1949): 41.

24. For further analysis on the historical development of the principle of double effect, see Christopher Kaczor, "Double-Effect Reasoning from Jean Pierre Gury to Peter Knauer," *Theological Studies* 59 (1998): 297-316; Thomas Cavanaugh, "Aquinas' Account of Double Effect," *Thomist* 61 (1997): 107-121; James Keenan, "The Function of the Principle of Double Effect," *Theological Studies* 54 (1993): 294-315; and Joseph Boyle, "Double Effect and a Certain Kind of Embryotomy," *Irish Theological Quarterly* 44 (1977): 303-318.

25. Gerald Kelly, S.J., *Medico-Moral Problems* (St. Louis, MO: The Catholic Hospital Association of the United States and Canada, 1958), 13-14.

26. Moraczewski, "Managing Tubal Pregnancies: Part II," 4.

27. William E. May, "Methotrexate and Ectopic Pregnancy," *Ethics & Medics* 23 (March 1998): 1. Emphasis in the original.

28. Ibid., 2. Emphasis in the original.

29. May quotes Drs. Thomas Hilgers and John Bruchalski to reinforce his position. May states: "Hilgers and Bruchalski inform me that the alleged medical benefits to the mother of using MTX or of a salpingostomy can be seriously questioned, and both judge MTX and salpingostomy to be direct attacks on the life of the unborn, not mere 'removals.' " Ibid.

30. Ibid .

31. "A 'slippery slope' or 'edge' argument raises questions about precedents that will be set and the consequences that may follow if a particular practice is accepted." For a more detailed analysis, see Carol Levine, *Cases in Bioethics: Selections from the Hastings Center Report* (New York: St. Martin's Press, Inc., 1989), 290.

32. Ibid., 3.

33. Ibid.

34. Boyle, 315-316.

35. Tuohey, 55.

36. James J. Walter, "Proportionate Reason and its Three Levels of Inquiry: Structuring the Ongoing Debate," *Louvain Studies* 10 (Spring 1984): 32.

37. McCormick's criteria for proportionate reason first appeared in Richard McCormick, *Ambiguity in Moral Choice* (Milwaukee, WI: Marquette University Press, 1973). He later reworked the criteria in response to criticism. His revised criteria can be found in, *Doing Evil to Achieve Good*, eds. Richard McCormick & Paul Ramsey (Chicago, IL: Loyola University Press, 1978).

38. See Louis Janssens, "Norms and Priorities in a Love Ethics," *Louvain Studies* (Spring 1977): 213-214. See also Gula, 273.

39. Thomas J. O'Donnell, S.J., *Morals in Medicine* (Westminister, MD: The Newman Press, 1960), 25. For a more detailed analysis of probabilism, see Albert R. Jonsen & Stephen Toulmin, *The Abuse of Casuistry: A History of Moral Reasoning* (Berkeley, CA: University of California Press, 1988), 164-175, 250-265; and Henry Davis, S.J., *Moral and Pastoral Theology*, Vol. 1 (New York: Sheed & Ward, 1958), 91-115.

40. Davis, 95.

41. Tuohey, 55.

42. For a more detailed analysis of their ethical positions concerning the moral distinction between the direct killing of an unborn child and the morally justifying reasons for tolerating the evil effect of the foreseen but unintended death of the embryo, see Germain Grisez, *Abortion: The Myths, the Realities, and the Arguments* (New York: Corpus Books, 1970), 340-341; Boyle, "Double-effect and a Certain Type of Embryotomy," 303-318 and Patrick Lee, *Abortion and Unborn*

Human Life (Washington, DC: The Catholic University Press of America, 1996), 110-120.

43. See William E. May, "The Management of Ectopic Pregnancies: A Moral Analysis," in *The Fetal Tissue Issue,* eds. Peter J. Cataldo and Albert S. Moraczewski, O.P. (Braintree, MA: The Pope John XXIII Medical-Moral Center, 1994), 121-148; May, "Methotrexate and Ectopic Pregnancy," 1-3 and Kevin Flannery, S.J., "What is Included in a Means to an End?", *Gregorianum* 74 (1993).